

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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MERCK SHARP & DOHME CORP., :
CUBIST PHARMACEUTICALS LLC, :
OPTIMER PHARMACEUTICALS LLC, :
AND MSD INTERNATIONAL :
GMBH, : Civil Action No. 20-534 (CCC)(MF)
Plaintiffs, : Civil Action No. 15-6541 (CCC)(MF)
: (consolidated)
v. :
ACTAVIS LABORATORIES FL, INC., :
Defendant. :
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CONSENT JUDGMENT

Merck Sharp & Dohme Corp., Cubist Pharmaceuticals LLC, Optimer Pharmaceuticals LLC, and MSD International GmbH (collectively hereinafter "Merck"), and Actavis Laboratories FL, Inc. (hereinafter "Actavis"), the parties in the above-captioned action, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in the action, as follows:

IT IS this 1 day of November, 2021:

ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above actions and has personal jurisdiction over the parties.
2. As used in this Consent Judgment, (i) the term "Actavis Product" shall mean the drug product sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 208443 (the "Actavis ANDA"); (ii) the term "Licensed Patents" shall mean

United States Patent Number 7,906,489; United States Patent Number 8,586,551; United States Patent Number 7,378,508; United States Patent Number 7,863,249; and United States Patent Number 8,859,510; and (iii) the term “Affiliate” shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with Actavis; for purposes of this definition, “control” means (a) ownership, directly or through one or more intermediaries, of (1) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (2) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership, or (b) any other arrangement whereby an entity or person has the right to elect a majority of the Board of Directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

3. Unless otherwise specifically authorized, Actavis, including any of its Affiliates, successors and assigns, is enjoined from infringing the Licensed Patents, on its own part or through any Affiliate, by making, having made, using, selling, offering to sell, importing or distributing of the Actavis Product.¹

4. Compliance with this Consent Judgment may be enforced by Merck and its successors in interest, or assigns.

5. This District Court retains jurisdiction to enforce or supervise performance under this Consent Judgment and any related agreements.

¹ By stipulation entered on February 3, 2020, Actavis Pharma, Inc. and Teva Pharmaceuticals USA, Inc., including all affiliates and subsidiaries thereof, have agreed to be bound by this Consent Judgment. Dkt. 324.

6. All claims, counterclaims, affirmative defenses and demands in these consolidated actions are hereby dismissed with prejudice and without costs, disbursements or attorneys' fees to any party.

7. For the avoidance of doubt, nothing in this Consent Judgment prohibits Actavis or its Affiliates from filing or maintaining with the FDA a "Paragraph IV Certification" for the Actavis Product pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) (as amended or replaced) with respect to the Licensed Patents or any other patent which may be listed in the FDA Orange Book in connection with the Approved DIFICID Product solely for the purposes of receiving or maintaining final approval of the Actavis Product.

8. Nothing herein shall prevent FDA from granting Final Approval of Actavis's Abbreviated New Drug Application No. 208443.



Hon. Claire C. Cecchi, U.S.D.J.

We hereby consent to the form and entry of this Order:

s/ Charles M. Lizza

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